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FACSIMILE COVER SHEET

Examiner: P. Nolan **Group:** 1644

Date: December 20, 2004

Client Code: 0148

Facsimile No.: 703-872-9306

From: Alice O. Carroll

Subject:
Paper: **Declaration of Don E. Griswold, Ph.D. under 37 C.F.R. §1.132**
Docket No.: 0148.1135-010
Applicant: George Treacy
Serial No.: 09/942,075
Filing Date: August 28, 2001

Number of pages including this cover sheet: 38

Please confirm receipt of facsimile: Yes ___ No ___

Comments: Incomplete Pages 5 – 38 Missing

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	George Treacy		
Application No.:	09/942,075	Group Art Unit:	1644
Filed:	August 28, 2001	Examiner:	Nolan, P.
Confirmation No.:	6161		

For: ANTI-TNFα ANTIBODIES IN THERAPY OF ASTHMA

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P O Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on.

12/20/04 Linda Woodhouse
Date Signature

LINDA WOODHOUSE
Typed or printed name of person signing certificate

DECLARATION OF DON E. GRISWOLD, PH.D.
UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Don E. Griswold, Ph.D., declare and state that:

1. I have been employed at Centocor, Inc., 200 Great Valley Parkway, Malvern, PA 19355 since 2001, most recently as Senior Director and Head, Department of Immunobiology. I have been advised that Centocor is the assignee of the entire right, title and interest of the subject application.

2. I received my Ph.D. degree in Pharmacology from the University of Kansas Medical Center, Kansas City, Kansas in 1969. A copy of my curriculum vitae, which describes my educational and professional experience, is attached as Exhibit A.

3. I have published extensively in refereed publications, most of which have been focused in the areas of inflammation, immunopharmacology, and pulmonary and cutaneous pharmacology. A list of publications authored or co-authored by me is included as part of my curriculum vitae.

4. I have read the Office Action dated May 18, 2004, the Office Action dated August 21, 2003, and the art cited by the Examiner in the Office Actions, in particular the cited references of Konno *et al.* (*Int. Arch. Allergy Immunol*, 105:308-316 (1994)), Shah *et al.* (*Clin. Exper. Allergy*, 25:1038-1044 (1995)), and Lukacs *et al.* (*J. Immunol.*, 154:5411-5417 (1995)). I have also read the patent application and the presently pending claims that were rejected in the Office Action.

5. Konno *et al.* examined the influence of roxithromycin (RXM), a macrolide antibiotic, and polyclonal rabbit anti-mouse TNFα antibodies on cytokine appearance in mouse lung extract induced by lipopolysaccharide (LPS) inhalation and on bronchial responsiveness (BR) to methacholine (Mch) in LPS-treated mice. Although inhalation of LPS causes pulmonary inflammatory responses and an increase in BR, it is not considered as an animal model for asthma. Thus, results obtained using the LPS mouse model would not provide evidence for the treatment of asthma.

6. Shah *et al.* summarize the scientific rationale available in 1995 that supported TNFα as an attractive target for asthma. In particular, Shah *et al.* report results showing (1) increased levels of TNFα in sputum of patients with acute attacks of asthma; (2) increased number of cells expressing TNFα mRNA in bronchoalveolar lavage (BAL) fluid of stable atopic asthmatic subjects when compared to BAL of normal subjects; and (3) TNFα levels up

CURRICULUM VITAE

Don E. Griswold, Ph.D.

November, 2004

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DATE AND PLACE OF BIRTH: June 24, 1943, Newton, Kansas

EDUCATION:

Institution	Degree	Date Received	Major(s)
University of Kansas Medical Center Kansas City, Kansas	Ph.D.	1969	Pharmacology
Emporia State University Emporia, Kansas	B.A.	1965	Microbiology and Chemistry

EXHIBIT
A